

### **REMARKS**

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks presented herein, are respectfully requested.

Claims 2-3, 6-8, 13, 15, 18-21 and 30-31 are amended, claims 1, 4, 9-11, 16-17 and 22 are cancelled. Claims 20-21 are allowed. Claims 5, 23-26, and 28-29 have been withdrawn from consideration by the Examiner as a result of a Restriction Requirement. Thus, claims 2-3, 6-8, 12-15, 18-21, 27, and 30-31 are currently under examination.

Claims 2-3, 6-7, 13, 20-21 and 30-31 have been amended to recite an antisense nucleic acid. Support for this amendment can be found at various places in the specification including, for example, at page 1, lines 23-31.

Claim 8 has been amended to specify that the antisense nucleic acid is administered by injection into the tumor. Support for this amendment can be found at various places in the specification including, for example, in the originally-filed claims 8 and 11.

Claims 6-8, 18-19 have been amended to specify that the entire antisense nucleic acid is at least 90 % or 100 % complementary to and binds specifically to a contiguous portion of a nucleic acid that encodes a human manganese superoxide dismutase. Support for this amendment can be found at various places in the specification including, in the prior claims 6-8 and 18-19 as well as in the specification, for example, at page 6, lines 13-25, disclosing the control oligos that have a mismatched or scrambled sequence relative to oligo 2. Thus, Applicants submit that no new matter has been added as a result of these amendments.

Applicants notes that the Examiner has indicated that claim 8 links the invention of groups I-III, and that upon allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim is entitled to examination.

### **Claim Objections**

The Examiner objected to claim 31 as being dependent upon a rejected base claim, in particular claim 6. This objection is moot in view of Applicants' amendment to claim 6.

### 35 U.S.C. §112 Rejections of the Claims

#### *Second Paragraph Rejections*

The Examiner rejected claims 11, 13 and 30 under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is moot in view of Applicants' cancellation of claim 11 and amendment to claims 13 and 30.

#### *First Paragraph Rejections*

The Examiner rejected claims 8, 11-15, 18-19 and 27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner's enablement rejection is based on two grounds: the Examiner asserted that the specification does not reasonably provide enablement for (1) the treatment of any cancer (2) via any method of delivery. The Examiner stated that the specification is enabling for the treatment of breast cancer by intratumoral injection of the claimed antisense oligonucleotides. Applicants respectfully traverse.

Regarding the method of delivery, Applicants have amended the claims to specify that the antisense nucleic acid is administered by injection into the tumor.

Regarding the treatment of cancer generally, Applicants respectfully submit that the Examiner has not met the initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention. See M.P.E.P. § 2164.04 citing *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) for the principle that the Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure.

The Examiner cited the teaching of Church *et al.* (*Proc. Nat'l. Acad. Sci.* 90:3113-117 (1993)) establishing that the malignancy of human melanoma cells is suppressed by increasing manganese superoxide dismutase expression as evidence that the claimed invention cannot work over its entire breadth. Applicants respectfully traverse. The instant claims are directed to a method of treating a tumor in a mammal comprising reducing antioxidant enzyme levels in a cell of the tumor by administering an antisense nucleic acid that binds specifically with a nucleic acid encoding human manganese superoxide dismutase. Thus, as claimed, the present invention is directed to treating a particular type of tumor, specifically, that which expresses manganese

superoxide dismutase. The Church *et al.* study, on the other hand, relates to treating a different type of tumor, in particular, tumors that express little of any manganese superoxide dismutase. See Church *et al.*, page 3115 (describing the human melanoma cell line as having “little steady-state MnSOD expression of *any* sense MnSOD RNA species”) (emphasis added). Because the Church *et al.* teaching relates to a different type of tumor, the Church *et al.* teaching is irrelevant to the patentability of the instant claims.

Accordingly, Applicants respectfully submit that claims 8, 12-15, 18 and 19 are fully enabled and request the Examiner reconsider and withdraw the 35 U.S.C. § 112, first paragraph, rejection of these claims.

### **35 U.S.C. § 102 Rejection of the Claims**

The Examiner rejected claims 2-3 and 6-7 under 35 U.S.C. § 102(b) as being anticipated by Kinscherf *et al.*, FASEB J. 12:461-467 (1998). In particular the Examiner alleges that Kinscherf *et al.* teach an antisense nucleic acid sequence containing phosphorothioate linkages that is 22 nucleotides in length and is 100 % complementary to the start codon of the nucleic acid encoding the human manganese superoxide dismutase. The Examiner alleges that, as claimed, the entire oligonucleotide sequence does not need to be at least 90 % or 100 % complementary to a contiguous portion of a nucleic acid that encodes a human manganese superoxide dismutase.

As amended, independent claims 6-7 specify that the entire antisense nucleic acid is at least 90 % or is 100 % complementary to and binds specifically to a contiguous portion of a nucleic acid that encodes a human manganese superoxide dismutase.

The amendment to claims 6-7 moots the 35 U.S.C. § 102(b) rejection of claims 2-3 and 6-7. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection.

**CONCLUSION**

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 373-6913 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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This paper or fee is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 7 day of January, 2008.

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